

REC 003101
AU Schneider, NG
TTL Use of 2 mg and 4 mg Nicotine Gum in an Individual Treatment Trial
CT The Pharmacologic Treatment of Tobacco Dependence: Proceedings of the
World Congress, November 4-5, 1985 (Smoking Behavior and Policy
Conference Series) pp. 233-248
DT
SUM The expectation of a "cure-all" is an obvious problem. Smoking is a
complex interaction of multiple forms of reinforcement. For most
smokers, it is unlikely that any pharmacological agent will suffice,
in itself, in producing long-term success. (p. 237)
SUBJ K1AB, CESSATION, METHODS, PHARMACOLOGICAL
CD JANUARY 1, 1988 SHB

REC 003102
AU Schneider, NG
TTL Use of 2 mg and 4 mg Nicotine Gum in an Individual Treatment Trial
CT The Pharmacologic Treatment of Tobacco Dependence: Proceedings of the
World Congress, November 4-5, 1985 (Smoking Behavior and Policy
Conference Series) pp. 233-248
DT
SUM The basis or rationale for nicotine replacement is to alleviate or
prevent withdrawal symptoms and craving while the person extinguishes
the smoking habit. This assumes withdrawal symptoms are
nicotine-specific. However, are all symptoms nicotine-specific? In
our placebo controlled trial (9), we found that 2 mg nicotine gum
alleviated some but not all symptoms reported by smokers. (pp.
237-238); This is consistent with Hughes and colleagues (3),
Hatsumkami and colleagues (2), and West and colleagues (12) who also
found that not all symptoms are alleviated with nicotine replacement
in gum form. (p. 239)
SUBJ K1ABA, CESSATION, METHODS, PHARMACOLOGICAL, NICOTINE REPLACEMENT

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CD JANUARY 1, 1988 SHB

SHOOK, HARDY & BACON ADDICTION DATA BASE

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CONFIDENTIAL
ATTY. WORK PRODUCT

REC 000704
AU Schneider,NG; Jarvik,ME; Forsythe,AB; Read,LL; Elliott,ML;
Schweiger,A
TTL Nicotine Gum in Smoking Cessation: A Placebo-Controlled,
Double-Blind Trial
CT Addict Behav 8(3): 253-261 [Jaffe expert report article #49]
DT 1983
SUM . . . In the present study, nicotine gum may have alleviated
withdrawal sufficiently to allow the subject's own coping devices to
extend the abstinence period. Unfortunately, ignorance of the
withdrawal process and the contributions of psychological vs.
pharmacological withdrawal reduce such suggestions to speculation.
For example, irritability or tension can result from cessation of
non-drug habits (gambling, nail-biting) or love loss; in cigarette
cessation, to what degree is reported tension a function of habit
loss vs. nicotine loss? . . . (p. 259)
SUBJ I1A, WITHDRAWAL, NICOTINE
CD MARCH 1, 1987 SHB

REC 000703
AU Schneider,NG; Jarvik,ME; Forsythe,AB
TTL Nicotine vs. Placebo Gum in the Alleviation of Withdrawal During
Smoking Cessation
CT Addict Behav 9: 149-156 [Jaffe expert report article #48]
DT 1984
SUM Withdrawal from smoking has been a difficult process to describe and
quantify (Shiffman, 1979). Individual variability in reports of
withdrawal accounts for some of the difficulty. Another problem lies
in the assessment of symptoms. Symptoms reported during smoking
cessation are also common responses to life stress and the cessation
of non-drug habits. In addition, the confounding of psychosocial and
pharmacological reinforcement systems in smoking has made it
difficult to determine the 'cause' of withdrawal during abstinence.
(pp. 154-155)
SUBJ I1A, WITHDRAWAL, NICOTINE
CD MARCH 1, 1987 SHB

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SHOOK, HARDY & BACON ADDICTION DATA BASE

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CONFIDENTIAL
ATTY. WORK PRODUCT

REC 001245
AU Schneider,NG; Jarvik,ME
TTL Nicotine Gum vs Placebo Gum: Comparisons of Withdrawal Symptoms and Success Rates
CT Pharmacological Adjuncts in Smoking Cessation 1
DT 1985
SUM In several of the initial gum studies, titration was the focus of study (Brantmark et al. 1973; Russell et al. 1976B; Turner et al. 1977). In the first two studies, active gum reduced tobacco consumption compared to placebo controls. However, the efficacy of nicotine gum is best studied when total smoking abstinence is required. Several efforts to study total cessation with nicotine gum were marred by lack of chemical verification (e.g., Puska et al 1979), absence of long-term followup (e.g., Malcolm et al, 1980) or inadequate controls. Raw et al. (1980) found improved cessation rates with nicotine gum but compared those results to a "psychological" control tested 2 years earlier.
SUBJ E1H, MOTIVATIONS, NICOTINE GUM
CD APRIL 2, 1987 JD/WC
UDT MAY 1, 1987 SHB

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SHOOK, HARDY & BACON ADDICTION DATA BASE

Date: 05/14/88

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CONFIDENTIAL
ATTY. WORK PRODUCT

REC 001246
AU Schneider, NG; Jarvik, ME
TTL Nicotine Gum vs Placebo Gum: Comparisons of Withdrawal Symptoms and Success Rates
CT Pharmacological Adjuncts in Smoking Cessation 1
DT 1985
SUM In several of the initial gum studies, titration was the focus of study (Brantmark et al. 1973; Russell et al. 1976B; Turner et al. 1977). In the first two studies, active gum reduced tobacco consumption compared to placebo controls. However, the efficacy of nicotine gum is best studied when total smoking abstinence is required. Several efforts to study total cessation with nicotine gum were marred by lack of chemical verification (e.g., Puska et al 1979), absence of long-term followup (e.g., Malcolm et al, 1980) or inadequate controls. Raw et al. (1980) found improved cessation rates with nicotine gum but compared those results to a "psychological" control tested 2 years earlier.; In summary, initial use and prolonged use of nicotine gum may both figure prominently in outcome. We cannot conclude from the present work that the enhancement of success with clinical support is due to psychological factors alone. Use variables (dose, number of pieces, length of time on gum, instructions) must be defined through controlled evaluation. We suggest that appropriate dose and carefully instructed use are critical and that intervention should focus on long-term relapse prevention. Ultimately, a combination consisting of physicians advising patients to stop, treatment of pharmacological dependence, and long-term behavioral training and support could provide the most valuable smoking cessation intervention to date.; The data in figure 2 indicate that neither 2 mg nor placebo gum was effective in cessation when no support or guidance was offered.
SUBJ K1ABA, CESSATION, METHODS, PHARMACOLOGICAL, NICOTINE REPLACEMENT
CD APRIL 2, 1987 JD/WC
UDT MAY 1, 1987 SHB

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SHOOK, HARDY & BACON ADDICTION DATA BASE

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CONFIDENTIAL
ATTY. WORK PRODUCT

REC 001247
AU Schneider,NG; Jarvik,ME
TTL Nicotine Gum vs Placebo Gum: Comparisons of Withdrawal Symptoms and Success Rates
CT Pharmacological Adjuncts in Smoking Cessation 1
DT 1985
SUM In several of the initial gum studies, titration was the focus of study (Brantmark et al. 1973; Russell et al. 1976B; Turner et al. 1977). In the first two studies, active gum reduced tobacco consumption compared to placebo controls. However, the efficacy of nicotine gum is best studied when total smoking abstinence is required. Several efforts to study total cessation with nicotine gum were marred by lack of chemical verification (e.g., Puska et al 1979), absence of long-term followup (e.g., Malcolm et al, 1980) or inadequate controls. Raw et al. (1980) found improved cessation rates with nicotine gum but compared those results to a "psychological" control tested 2 years earlier.
SUBJ K1AD, CESSATION, METHODS, CRITICISM
CD APRIL 2, 1987 JD/WC
UDT MAY 1, 1987 SHB

REC 002849
AU West,R; Schneider,N
TTL Craving for Cigarettes
CT Br J Addict 82: 407-415
DT 1987
SUM Craving is a feature of addictions as diverse as compulsive gambling and alcoholism. (p. 407)
SUBJ A1G, TERMS, CRAVING
CD NOVEMBER 1, 1987 SHB

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